

February 22, 2001

**PATIENT CARE SERVICES INFORMATION LETTER**

**PROTOCOL FOR SHARING NATIONAL PROSTHETIC PATIENT DATABASE WITH  
VA AND NON VA RESEARCH INVESTIGATORS**

1. This information letter describes the protocol by which the Department of Veterans Affairs (VA) and non VA researchers may access data stored in the National Prosthetic Patient Database (NPPD) at the Chief Information Officer (CIO) field office in Hines, IL.
2. The National Prosthetic Patient Database (NPPD), developed and implemented by the Prosthetic and Sensory Aids Service Strategic Healthcare Group (PSAS SHG), is an established central database of Prosthetics data recorded at each Veterans Health Administration (VHA) facility. The NPPD menu provides patient specific identifiers such as patient information, patient eligibility, prosthetic treatment, date of provision, cost, vendor, and purchasing agent information. NPPD tracks average cost data and its usage and will provide on a quarterly basis detailed and summary reports by station, Veterans Integrated Services Network (VISN) and agency. The NPPD menu resides in the Veterans Health Information Systems and Technology Architecture (VistA) at the medical center level. This data is updated quarterly. Data is rolled up at each facility and transmitted to the CIO field office in Hines, IL.
3. Currently, access to NPPD is strictly limited to authorized Information Service Center (ISC) staff and VA personnel and is accessed and updated via modem. Access is obtained through unique access codes, which are changed periodically. VA personnel are bound by all legal and ethical requirements to protect the rights of Research and Development subjects, including the confidentiality of information that can be identified with a person (M-3, Chapter 9, subpar, 9.14a).
4. VHA has an obligation to protect its patients from research risks, including risks to the privacy and confidentiality of patient information. Specifically, Institutional Review Boards (IRBs) review proposals to determine whether potential risks to human subjects are ethically justified. According to federal regulations, studies involving identifiable patient information are defined as human subjects research.
5. The process described in this Information Letter to request permission to access NPPD reflects current VA policy.

a. **NOTE:** M-3, Chapter 9, subparagraph 9.14b applies to VA personnel who wish to use patient information from other VA facilities for VA approved research projects. VA personnel may obtain and use for approved Research and Development purposes medical, technical, and administrative records from other VA facilities as well as those available locally. Requests for records from other facilities must be endorsed by the local VA Institutional Review Board and the facility Director before being submitted for final approval to the appropriate Research and Development service director (12\_\_) in VA Central Office, through the Chief Consultant, PSAS SHG (113), VA Central Office.

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b. **NOTE:** *M-3, Chapter 9, subparagraph 9.14c applies to non-VA personnel who wish to use VA patient information.* Persons not employed by the VA can only be given access to medical and other VA records for Research and Development purposes within the legal restrictions imposed by such laws as the Privacy Act of 1974 and Title 38 United States Code (U.S.C.). Requests for such use must be endorsed by the IRB that has a cooperative agreement with a VA facility before being submitted for final approval to the Chief Officer, Research and Development (12) in VA Central Office, through the Chief Consultant, PSAS SHG (113), VA Central Office, at least 60 days before access is desired. A request for information filed pursuant of the Freedom of Information Act ordinarily requires a response within 20 working days. VA will adhere to these guidelines when such requests are received so that a timely reply can be made.

c. The formal written and signed request (memo or letter format) from the principal investigator must contain the following:

(1) A one page document describing the project (Executive Summary or Abstract is acceptable), cover sheet of the approved Merit Review or Pilot Application, and a copy of the letter of approval from the local VA Research and Development Committee and the facility director or other appropriate research agency.

(2) The specific NPPD variable(s) needed to accomplish the objectives within the approved VA research protocol.

(3) If patient Social Security Number (SSN) disclosure is required for the effective use of the database, provide special documentation for the need, e.g., the principal investigator requires linking of the database to the VA Patient Treatment File (PTF).

(4) A completed and signed Privacy Act and Data Security Statement (see Att. A).

(5) A copy of the IRB endorsement.

6. The researcher is responsible for any cost accrued by VHA for access or use of the database, and those costs should be incorporated into the full research proposal. Questions concerning the contents of this Information Letter may be directed to Frederick Downs, Jr., Chief Consultant, PSAS SHG at 202-273-8515.

S/ Thomas V. Holohan, M.D., FACP  
Chief Patient Care Services Officer

Attachment

**DISTRIBUTION:** CO: E-mailed 3/2/2001  
FLD: VISN, MA, DO, OC, OCRO, and 200 – E-mailed 3/2/2001

**ATTACHMENT A**

**SAMPLE FORMAT OF  
PRIVACY ACT AND DATA SECURITY STATEMENT FOR RESEARCH,  
AUDIT AND EVALUATION ACTIVITIES INVOLVING RELEASE OF  
IDENTIFIABLE PATIENT DATA GOVERNED BY THE PRIVACY ACT,  
TITLE 38 UNITED STATES CODE (U.S.C.) 5701 AND/OR U.S.C. 7332**

**1. Title of Research, Audit or Evaluation Activity:**

**2. Patient Data Elements to Be Used:**

**3. Name(s) of Database(s) for Which Access is Required:**

**4. Delimiting Dates of Access for Research, Audit or Evaluation Activity:**

**5. Limitation on Use and Redisclosure:** All identifying data is to be kept strictly confidential by the Department of Veterans Affairs (VA) personnel and is to be used only for the research, audit or evaluation purposes described herein. At the end of the project all data files with veteran identifiers are to be erased or destroyed. Results generated from this research, audit, or evaluation containing identifiers may be disclosed only back to VA, and no identity will be made of any individual patient in any report of the research, audit, or evaluation or otherwise disclose patient identifiers.

**6. Data Security:** Data containing patient names or identifiers need to be securely stored and protected from theft by the use of passwords (when data are stored on hard disks) and locked cabinets (when the data are stored on floppy disks or any other transportable medium). Patient level data is not to be disclosed, copied, or transmitted in total or in part to anyone not connected with the approved protocol.

**7. Penalty Provisions:** Penalties for misuse of the data provided are set at not more than \$5,000 for the first offense and not more than \$20,000 in the case of any subsequent offense. (Title 5 United States Code (U.S.C.) 552a, 38 Code of Federal Regulations (FR), 1.576 (e) and 1.463).

**8. Certification:** As principal investigator, I hereby acknowledge that I am responsible for the research data and understand and agree to the provisions as set forth above. I am responsible for ensuring all individuals participating in this investigations study comply with the provisions as set forth above. This release of identifying patient information is approved, only for the purposes and under the conditions described in the preceding, under the provision of the Privacy Act, 5 U.S.C. 552a(a)(8)(B)(ii) and (b)(3), and routine use #15 as set forth in the VA System of Records Notice "24VA136, Patient Treatment Records" and 38 U.S.C. 7332(b)(2)(B) and VA regulations 38 CFR 1.488 through 1.489.

**RESPONSIBLE RESEARCH OFFICIAL(S)**

**Name:**  
**Title:**  
**Address:**

**E-mail Address:**  
**Phone Number:**  
**Signature and Date:**

**REVIEWING AND APPROVING VA OFFICIALS**

**Name:** John R. Feussner, M.D.  
**Title:** Chief Officer, Research and Development (12)  
**Address:** Department of Veterans Affairs, 810 Vermont Avenue, NW,  
Washington, DC 20420  
**Phone Number:** (202) 273-8284  
**E-mail Address:** [Feussner.John@mail.va.gov](mailto:Feussner.John@mail.va.gov)

**Name:** Frederick Downs, Jr.  
**Title:** Chief Consultant, Prosthetic and Sensory Aids Service SHG (113)  
**Address:** Department of Veterans Affairs, 810 Vermont Avenue, NW,  
Washington, DC 20420  
**Phone Number:** (202) 273-8515  
**E-mail Address:** [Downs.Fred@mail.va.gov](mailto:Downs.Fred@mail.va.gov)

**Date:**